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October 3, 2005

Honorable Gregory M. Sleet
United States District Court for the District of Delaware
J. Caleb Boggs Federal Building
844 N. King Street, Lockbox 18
Wilmington, DE 19801

Re: Enzon Pharmaceuticals, Inc. v. PhoenixPharmacologics, Inc.
C.A. No. 04-1285-GMS

Dear Judge Sleet:

Phoenix Pharmacologics, Inc. ("Phoenix") hereby requests permission to file a motion for summary judgment that Enzon Pharmaceuticals, Inc. ("Enzon") is not entitled to sole ownership of U.S. Patent No. 6,183,738 ("the 738 patent"), as sought in Count II of Enzon's Amended Complaint.

It is undisputed that Enzon's employees did not conceive all of the inventions that are recited in the 738 Patent claims. In fact, Phoenix's assignee, Dr. Mike Clark, the named inventor of the patent, conceived claimed inventions after he left Enzon's employ. At the very least, then, Dr. Clark is a co-inventor of the 738 Patent, and Phoenix, his assignee, has an ownership interest in the patent.

Background

This is a civil action initiated by Enzon under 35 U.S.C. § 256 to change the inventorship of the 738 Patent and to compel Phoenix to assign to Enzon all the rights in the patent that Phoenix received by assignment from Dr. Mike Clark. Dr. Clark is Phoenix's co-founder and the sole inventor named on the 738 Patent.

The 738 Patent issued in 2001 based on a patent application that Dr. Clark filed in 1997. The patent is directed to chemical compounds that can be used, for example, to treat certain types of cancer. The compounds disclosed and claimed in the patent generally include three components: (1) a specific type of protein, known as arginine deiminase ("ADI"), that can be derived from certain microorganisms; (2) a polymer, known as polyethylene glycol ("PEG"); and (3) a linker that is positioned between the ADI component and the PEG component to connect them. The issued claims of the 738

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patent are directed to compounds of this type that include specific types of linkers, specific sizes of PEG polymers, and/or ADI from specified microorganisms.

In 1994, Enzon hired Dr. Clark, who had worked on ADI at another company, to supervise its research into ADI and other therapeutic agents. Enzon's research involved attaching PEG polymers to ADI derived from two microorganisms, *Mycoplasma arginini* and *Pseudomonas putida*.

In the spring of 1996, Enzon implemented a reduction-in-force that resulted in the dismissal of a number of individuals, including Dr. Clark. Following Dr. Clark's dismissal, he joined the Ludwig Institute for Cancer Research and continued researching ADI-PEG as a potential anti-cancer treatment. At the Ludwig Institute, Dr. Clark made several discoveries. For example, Dr. Clark found that ADI derived from the organism *Mycoplasma hominus* was as effective as ADI derived from *Mycoplasma arginini* but was not as toxic.

Based on the success of his research at the Ludwig Institute, Dr. Clark formed Phoenix to further develop the ADI-PEG molecules that he had identified at the Institute. In 1997, Dr. Clark filed the first patent application upon which the 738 Patent is based, and assigned it to Phoenix. Claim 6 of the patent is directed to ADI-PEG compounds wherein, *inter alia*, the ADI is derived from a microorganism that is selected from the group consisting of *Mycoplasma hominus*, *Mycoplasma arginini*, *Mycoplasma arthritides*, and combinations thereof.

Law & Argument

The Court should grant Phoenix's summary judgment motion because it is beyond dispute that Enzon's employees did not conceive all of the inventions that are claimed in the 738 Patent. There is no factual dispute, for example, that after Dr. Clark left Enzon he conceived at least the claimed compounds in which ADI is derived from *mycoplasma hominus*. Accordingly, Enzon is not entitled to sole ownership of the 738 Patent.

Summary judgment is proper if it is shown that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *Chimie v. PPG Indus. Inc.*, 402 F.3d 1371, 1376 (Fed. Cir. 2005). Where the non-movant bears the ultimate burden of proof on the merits, as Enzon does here on conception, "Rule 56(c) mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a [non-moving] party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex*, 477 U.S. at 322-23.

The issuance of a patent creates a presumption that its named inventor is the true and only inventor. *Hess v. Advanced Cardiovascular Sys.*, 106 F.3d 976, 980 (Fed. Cir. 1997). To rebut this presumption, a district court must find clear and convincing evidence that the alleged unnamed inventor was in fact an inventor before correcting

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inventorship under 35 U.S.C. § 256. *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1350 (Fed. Cir. 1998).

To be an inventor, one must make a significant contribution to the conception of one or more claims of the patent. *Fina Oil & Chem. Co. v. Ewen*, 123 F.3d 1466, 1473 (Fed. Cir. 1997). Conception, in turn, is the "formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice." *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1206 (Fed. Cir. 1991) (quoting *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376 (Fed. Cir. 1986). "Conception must include every feature or limitation of the claimed invention." *Slip Track Systems, Inc. v. Metal-Lite, Inc.*, 304 F.3d 1256, 1263 (Fed. Cir. 2002).

There Is No Factual Dispute That Enzon Employees Did Not Conceive All Of The Inventions That Are Recited In The 738 Patent Claims

It is beyond dispute that Enzon employees did not conceive at least the compounds claimed in the 738 Patent in which the ADI component of such compounds is derived from *Mycoplasma hominus*. It is undisputed that Enzon's ADI-PEG research during Dr. Clark's employment at Enzon did not involve attaching PEG polymers to ADI derived from this organism. For example, Enzon's Rule 30(b)(6) witness on conception of the claimed inventions, David Filpula, admitted that Enzon had not conceived of attaching a PEG polymer to ADI derived from *Mycoplasma hominus*. Testimony consistent with that provided by Dr. Filpula was provided by Stanford Lee, the sole individual whom Enzon alleges to have conceived the claimed inventions.

Since there is no genuine factual dispute that an Enzon employee did not conceive of attaching a PEG group to ADI that was derived from *Mycoplasma hominus*, and since such compounds are expressly recited in the 738 Patent claims, summary judgment that Enzon's employees did not conceive all of the inventions that are recited in the claims is appropriate.

Conclusion

Phoenix respectfully requests that the Court grant permission for Phoenix to file a motion for summary judgment finding that no one at Enzon conceived of the full scope of the 738 Patent claims.

Respectfully submitted,



Richard D. Kirk

RDK/slh

cc: Courtesy copy to Clerk by hand
Counsel as shown on attached certificate

CERTIFICATE OF SERVICE

The undersigned counsel certifies that, on October 3, 2005, he electronically filed the foregoing document with the Clerk of the Court using CM/ECF, which will send automatic notification of the filing to the following:

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The undersigned counsel further certifies that copies of the foregoing document were sent by email and hand to the above local counsel and by email and U.S. mail to the following non-registered participants:

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/s/ Richard D. Kirk (rk0922)